UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

FWK HOLDINGS, LLC, MEIJER, INC., AND MEIJER DISTRIBUTION, INC., Plaintiffs, v. TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., ENDO INTERNATIONAL PLC, AND PAR PHARMACEUTICAL, INC., Defendants.	Civil Action No. _____

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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1. Plaintiffs FWK Holdings, LLC, Meijer, Inc., and Meijer Distribution, Inc. (collectively, the "direct purchaser plaintiffs") bring this civil antitrust class action, on behalf of themselves and all others similarly situated, against Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., Endo International plc, and Par Pharmaceutical, Inc., based on personal knowledge as to themselves and upon information and belief as to all other allegations, and allege as follows.

I. INTRODUCTION

2. In late 2014, pharmaceutical giant Takeda paid generic competitor Par to keep generic Amitiza, an anti-constipation drug, off the market for up to six more years. The deal preserved Amitiza's monopoly, and with it Amitiza's monopoly profits which were shared between Takeda and Par.[1]

3. The active pharmaceutical ingredient in Amitiza is lubiprostone. The Takeda-Par deal came just after the lubiprostone compound patent expired in 2014, leaving only weak, easily-designed-around patents standing in the way of generic market entry. Takeda's payment to Par took the form of a de facto, extra-long no-authorized-generic ("no AG") agreement, guaranteed to restrict competition once Par eventually entered with a generic and thus ensuring Par could charge higher prices than it would with other generic competition on the market. Takeda's payment to Par was intended to delay, and had the effect of delaying, full competition in the market for generic Amitiza.

4. Par's agreement did not just delay Par's entry; it delayed all generic entry. At least six companies filed applications to market and sell generic Amitiza. But by regulation, no other generics could enter before Par, as the first generic to seek approval. And for its

[1] Though Takeda did not create Amitiza, it had taken helm of the franchise through a commercialization agreement with Sucampo, the original creator of the drug and holder of FDA approval and patents claiming to cover Amitiza.

agreement to stay off the market until January 2021 and block other generics in the process, Par was rewarded handsomely: Takeda and Sucampo (the Amitiza NDA holder that gave marketing and commercialization responsibilities to Takeda) agreed that they would not launch an authorized generic version of the product not only during Par's six-month period of regulatory exclusivity as the first-to-file generic, but apparently for another year-and-a-half thereafter—that is, the no AG agreement here lasted *300% longer* than the even the typical no AG agreement found unlawful in many similar cases, including by a jury in this District. Per the settlements with later ANDA filers, other Amitiza generics will not enter before January 2023. Takeda's no AG payment to Par was worth at least $29 million and as much as $280 million, far more than Par would have earned even had it prevailed in the patent litigation. And, as a result of delayed generic competition allowing Takeda to monopolize the market with its brand Amitiza product for years at a supracompetitive price, purchasers paid far more and Takeda and Par made many hundreds of millions of dollars more than they otherwise would have.

5. Had Takeda and Par resolved their dispute without a payment, the plaintiffs and members of the class would have been able to purchase Amitiza's generic equivalents earlier and for far less money. Instead, they have suffered many hundreds of millions of dollars in overcharges as a result of the defendants' conduct. The plaintiffs seek to recover for those overcharges.

II. PARTIES

6. Plaintiff FWK Holdings, LLC ("FWK") is a limited liability company organized under the laws of the state of Illinois, with its principal place of business located in Glen Ellyn, Illinois. FWK is the assignee of the claims of the Frank W. Kerr Company, which, during the class period, as defined below, purchased brand Amitiza directly from Takeda at

supracompetitive prices, and therefore suffered antitrust injury as a result of the anticompetitive conduct alleged herein.

7. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc., (collectively, "Meijer") are corporations organized under the laws of the state of Michigan, with their principal place of business located at 2929 Walker Avenue, NW, Grand Rapids, Michigan 49544. Meijer is the assignee of the claims of McKesson Corporation, which, during the relevant period, purchased brand and authorized generic Amitiza directly from Takeda and Par at supra-competitive prices as a result of the anticompetitive conduct alleged herein.

8. Defendant Takeda Pharmaceutical Company Limited ("Takeda Japan") is a Japanese corporation having a principal place of business at 1-1, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo, Japan. Takeda Japan owns and controls Takeda Pharmaceuticals U.S.A., Inc., the operative company behind the events alleged herein.

9. Defendant Takeda Pharmaceuticals U.S.A., Inc. ("Takeda U.S.A.," together with Takeda Japan, "Takeda") is a corporation jointly owned by Takeda Japan and another Takeda Japan subsidiary, non-party Takeda Pharmaceuticals International, AG. Takeda's principal place of business is at 95 Hayden Avenue, Lexington, MA 02421. As Takeda's website states: "Massachusetts serves as the U.S. hub for several global business operations, including the U.S. Commercial Business Unit, Global R&D, Global Oncology, Global Vaccines, Biologics Manufacturing and Cell Therapy Manufacturing." At all relevant times, Takeda was the only entity selling branded Amitiza in the United States.

10. Defendant Par Pharmaceutical, Inc. ("Par") is a New York corporation with its principal place of business in Chestnut Ridge, New York. Par is a subsidiary of Endo International plc ("Endo"). In September 2015, Endo completed an acquisition of Par Pharmaceuticals Holdings, Inc. and its subsidiaries, including Par, and combined it with Endo's

existing generics subsidiary, Qualitest Pharmaceuticals. As used in this complaint, "Par" encompasses relevant predecessors- and successors-in-interest.

11. Defendant Endo International plc ("Endo") is an Irish corporation with its U.S headquarters located in Malvern, Pennsylvania. Endo owns and controls Par, the operative company behind the events alleged herein.

12. All of the defendants' wrongful actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the defendants.

III. JURISDICTION AND VENUE

13. This action alleges violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, that are actionable under section 4 of the Clayton Act, 15 U.S.C. § 15(a). The action seeks to recover treble damages, interest, costs of suit, and reasonable attorneys' fees for the injuries sustained by the plaintiffs and members of the class resulting from the defendants' conspiracy to monopolize and to restrain trade in the United States market for Amitiza and its generic equivalents.

14. The Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1337(a) (antitrust), and 15 U.S.C. § 15 (Clayton Act).

15. Venue is appropriate within this district under 15 U.S.C. § 15(a) (Clayton Act), 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28 U.S.C. §1391(b) (general venue provision). The defendants transact business within this district and the defendants transact their affairs and carry out interstate trade and commerce, in substantial part, in this district.

Further, the defendants and/or their agents may be found in this district.

16. The Court has personal jurisdiction over each defendant. Each defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY FRAMEWORK

A. The regulatory structure for approval and substitution of generic drugs.

17. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"),[2] manufacturers that create a new drug must obtain approval from the Food and Drug Administration ("FDA") to sell the product by filing a New Drug Application ("NDA").[3] An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.[4]

18. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") certain kinds of patents that the manufacturer asserts could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents.[5] The manufacturer may list in the Orange Book within 30 days of issuance any patents issued after the FDA approved the NDA.[6] Valid and

[2] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. § 301 et seq.).

[3] 21 U.S.C. §§ 301-392.

[4] 21 U.S.C. § 355(a), (b).

[5] For example, patents covering processes for making drug products may not be listed in the Orange Book.

[6] 21 U.S.C. § 355(b)(1), (c)(2).

infringed patents may lawfully prevent generic competition, at least for a period, but manufacturers can abuse the system to use invalid or non-infringed patents to unlawfully delay generic competition.

19. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability because it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments.

20. The Hatch-Waxman Amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.[7] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA and must show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, i.e., absorbed at the same rate and to the same extent as the brand. The FDA assigns a generic that meets these criteria relative to its brand counterpart an "AB" rating, making it an "AB-rated" generic.

21. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic is

[7] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart.[8]

22. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

23. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, revenues for brand and generic prescription drugs totaled $21.6 billion; by 2013, total prescription drug revenues had climbed to more than $329.2 billion, with generics accounting for 86% of prescriptions.[9] Generics are dispensed about 95% of the time when a generic form is available.[10]

2. The FDA may grant regulatory exclusivities for new drugs but those exclusivities do not necessarily bar generic entry.

24. To promote a balance between new drug innovation and generic drug competition, the Hatch-Waxman Amendments also provide for exclusivities (or exclusive marketing rights) for new drugs. The FDA grants any such exclusivities upon approval of a drug if the sponsor and/or drug meet the relevant statutory requirements. Any such exclusivities for a drug are listed in the Orange Book, along with any applicable patents, and

[8] 21 U.S.C. § 355(j)(8)(B).

[9] *See* IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013* 30, 51 (2014).

[10] *Id.* at 51.

can run concurrently with the listed patents.

25. One such exclusivity, the New Chemical Entity (NCE) exclusivity, applies to products containing chemical entities never previously approved by the FDA either alone or in combination. If a product receives NCE exclusivity, the FDA may not accept for review any ANDA for a drug containing the same active moiety for five years from the date of the NDA's approval, unless the ANDA contains a certification of patent invalidity or non-infringement, in which case an application may be submitted after four years.[11]

26. A drug product may also receive a three-year period of exclusivity if its sponsor submits a supplemental application (sNDA) that contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the supplemental application. If this exclusivity is granted, the FDA may not approve an ANDA for that drug for three years from the date on which the supplemental application is approved.[12]

27. Regulatory exclusivities may not be absolute bars to generic entry. For example, some can be overcome by carving out information in the label or for other reasons.[13]

3. The first ANDA filer to issue a paragraph IV certification is entitled, once approved, to 180 days as the only ANDA generic on the market.

28. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

a. That no patent for the brand has been filed with the FDA (a "paragraph I certification");

b. That any patent(s) for the brand has/have expired (a "paragraph II

[11] 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2).

[12] 21 U.S.C. § 355(j)(5)(F)(iv); 21 C.F.R. § 314.108(b)(2)(5).

[13] *See, e.g.*, 21 C.F.R. §§ 314.94(a)(8)(iv), 314.127(a)(7); 21 U.S.C. § 355a(o).

certification");

c. That any patent(s) for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a "paragraph III certification"); or

d. That any patent(s) for the brand is/are invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").[14]

29. Paragraph IV notifications are required by law to provide with specificity "a detailed statement of the factual and legal basis of the opinion of the applicant" that the challenged patents would not be infringed by the manufacture, use or sale of the ANDA product. 21 U.S.C. § 355(j)(2)(B).

30. If a generic manufacturer files a paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA-filer (which would enable the manufacturer to market and sell its product) until the earlier of (i) the passage of two-and-a-half years, or (ii) the issuance of a decision by a court that the patent at issue is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may only grant "tentative approval," but cannot authorize the generic manufacturer to market its product (i.e., grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA meets all regulatory requirements and is ready for final approval but for the 30-month stay.

31. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first paragraph IV generic manufacturer

[14] 21 U.S.C. § 355(j)(2)(A)(vii).

ANDA filer ("first-filer") a 180-day exclusivity period to market the generic version of the drug; the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug during that time.[15] That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until that first-filer generic(s) has been on the market for 180 days.[16]

32. The 180-day window is often referred to as the first filer's six-month or 180-day "exclusivity"; this is a bit of a misnomer, though, because a brand manufacturer can launch an authorized generic (AG) at any time, manufacturing its AG in accordance with its approved NDA for the branded product but selling at a lower price point.

33. A first filer who informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing generics.

4. Section viii carveouts and labeling can enable generics to lawfully enter the market despite a brand company's patents.

34. The Hatch-Waxman Act encourages generic manufacturers to seek approval of generic products for uses that do not infringe valid and enforceable patents. The Act recognizes that a generic may infringe one (patented) method of use without infringing another and encourages generics to "carve out" would-be infringing uses to bring products to market

[15] 21 U.S.C. § 355(j)(5)(B)(iv), (D).

[16] There is an exception: if the first-filer forfeits exclusivity. A first filer can forfeit its 180-day exclusivity by, for example, failing to obtain tentative approval from the FDA for its ANDA within 30 months of filing its ANDA. There is no forfeiture here.

quickly.

35. To carve out on a non-infringing use, an ANDA applicant may submit a section viii statement. A section viii statement asserts that the generic manufacturer will market the drug for one or more methods of use not covered by the brand's valid and enforceable patents. If an ANDA applicant files a section viii statement, the patent claiming the protected method of use will not serve as a barrier to ANDA approval.

36. A section viii statement is commonly used when the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug. The ANDA applicant then proposes labeling for the generic drug that "carves out" from the brand's approved label the still-patented methods of use.

37. Typically, the Hatch-Waxman Act requires that an ANDA contain "information to show that the labeling proposed for the new [generic] drug is the same as the labeling approved for the listed drug[.]" However, FDA regulations also expressly recognize that by submitting a section viii statement, an ANDA applicant may omit from the proposed labeling a method of use protected by a listed patent, and therefore need not seek approval for that use. As the Supreme Court has recognized, "[t]he statutory scheme, in other words, contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones."

38. Thus, under the statute, regulations, and applicable case law, the carve-out of patent-protected labeling is generally permitted if the omission does not render the proposed drug product less safe or effective for the conditions of use that remain in the labeling.

5. Patents are not bulletproof.

39. The existence of one or more patents purporting to cover a drug product does not guarantee a monopoly. Patents are routinely invalidated or held unenforceable, either upon reexamination or *inter partes* proceedings by the U.S. Patent and Trademark Office ("PTO"), by

court decision, or by jury verdict. At all times, a patent holder bears the burden of proving infringement.

40. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

41. A patent is invalid or unenforceable when: (i) the disclosed invention is anticipated or obvious in light of earlier prior art; (ii) when an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information known to that person to be material, or submits materially false information to the PTO during prosecution; and/or (iii) when a later acquired patent is not patentably distinct from the invention claimed in an earlier patent (and no exception, such as the safe harbor, applies).

42. In these circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

43. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002.[17] An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009

[17] FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* vi-vii (2002), *available at* https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (last accessed Feb. 14, 2020).

similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.[18]

44. In Hatch-Waxman patent litigation, the parties are disputing whether the at-issue patent(s) are valid and enforceable, and manufacture or sale of the generic company's proposed ANDA product would actually infringe the brand's patent(s). Typically, the position of the brand is that the patent(s) is valid, enforceable and would be infringed, and that settlement should provide for entry at or near expiry of the patent. The position of the generic is that the patent(s) is invalid, unenforceable and/or not infringed, so a settlement should provide for immediate or near immediate entry. The strength of these positions can vary by generic depending, e.g., on how successful each generic has been at formulating its product so as to avoid infringing the brand's patents. A settlement on the merits—with a compromised agreed entry date and without a reverse payment or other undue influence on the generic's bargaining position—directly reflects the probabilistic outcome of the litigation. That is, the stronger the generic manufacturer's patent position, the earlier the entry date. The weaker the generic's patent position, the later the entry date.

45. If a generic manufacturer successfully defends against the brand's infringement lawsuit—either by showing that its ANDA does not infringe any asserted patents and/or that any asserted patents are invalid or unenforceable—the generic may enter the market immediately upon receiving approval from the FDA.

B. The competitive effects of AB-rated generic and authorized generic competition.

46. Generic and authorized generic versions of brand name pharmaceutical drugs contain the same active ingredient(s) as the brand name drug and are determined by the FDA

[18] John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1787 (2014) ("[P]atentees won only 164 of the 636 definitive merits rulings, or 26%," and "that number is essentially unchanged" from a decade ago.).

to be just as safe and effective as their brand counterparts. The only material difference between generics and their corresponding brand versions is the price. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a branded product and its generic version, or between generic versions, is price. Typically, generics are at least 10% less expensive than their brand counterparts when there is a single generic competitor. This discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers, especially direct purchasers.

47. Since the passage of the Hatch-Waxman Amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic where the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic hits the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market within the first six months. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%.[19] As a result, generic competition is viewed by brand

[19] *See* FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), *available at* https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf ("FTC Pay-for-Delay Study") (last accessed Feb. 14, 2020).

manufacturers as a grave threat to their bottom lines.

48. Generic competition enables all direct purchasers of a drug to (i) purchase generic versions of the drug at substantially lower prices, and/or (ii) purchase the brand at a reduced price.

49. Until a generic version of the brand drug enters the market, however, there is no bioequivalent drug to substitute for and compete with the brand, and the brand manufacturer can therefore continue to profitably charge supracompetitive prices. Brand manufacturers, like Takeda, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible – including illegal means – to delay or prevent generic competition.

1. The first AB-rated generic is priced below the brand.

50. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.[20] Every state either requires or permits that a prescription written for the brand be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand. At the same time, there is a reduction in the average price paid for the drug at issue (brand and AB-rated generic combined).

51. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market (though the brand's AG can be, and often is, on the market during the 180-day exclusivity period). In the absence of competition from other generics, during the 180-day exclusivity period, a first-filer generic manufacturer generally makes about

[20] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii, vi, 34 (2011), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("FTC 2011 AG Study") (last accessed Feb. 14, 2020); FTC Pay-for-Delay Study at 1.

80% of all profits that it will ever make on the product.

2. Later generics drive prices down further.

52. Once generic competitors enter the market, the competitive process accelerates, and multiple generic manufacturers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[21]

53. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic results in a near term retail price reduction of around 10% as compared to the brand price, but that with two generic entrants the near term retail price reduction is about 50%.

54. In a report issued at the request of Congress in 2011, the FTC found that generics captured 80% or more of sales in the first six months.[22] (This percentage erosion of brand sales holds regardless of the number of generic entrants.) In the end, the brand manufacturer's sales decline to a small fraction of their level before generic entry. This is because, "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[23]

3. Authorized generics, like other generics, compete on price.

55. Nothing prevents a brand manufacturer from marketing and selling an AG at

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[21] *See, e.g.*, Tracy Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, 26 INT'L J. INDUS. ORG. 930 (2008); Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & ECON. 311 (2000).

[22] FTC 2011 AG Study at 66-67.

[23] *See* "What Are Generic Drugs?," FDA (Aug. 24, 2017), *available at* https://www.fda.gov/drugs/generic-drugs/what-are-generic-drugs (last accessed Feb. 14, 2020).

any time. An AG is chemically identical to the brand drug, but sold as a generic – typically through either the brand manufacturer's subsidiary (if it has one) or through a third-party distributor. An AG is essentially the brand product in a different package. A first filer's 180-day exclusivity period does not apply to a manufacturer selling an AG.

56. The FDA has found that allowing brand manufacturers to introduce AGs during the 180-day exclusivity period is consistent with the "fundamental objective of the Hatch-Waxman amendments": to encourage competition and, as a result, "lower prices in the pharmaceutical market."[24] The FDA reasoned that if a brand releases an AG at a reduced price during the 180-day exclusivity period, "this might reasonably be expected to diminish the economic benefit" to the generic first-filer by increasing competition and causing the generic to "reduc[e] the substantial "mark-up" [generics] can often apply during the [18-day] period."[25] Such competition, and the resulting price decreases, work to benefit drug purchasers.

57. Brand manufacturers, like Takeda and Sucampo, recognize the significant economic advantages of releasing their AGs during—or even before—the 180-day exclusivity period. One study notes that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[26]

58. Brand manufacturers can produce the AG at low-cost and low-risk, since AGs do not require FDA approval or additional R&D, and the brand already has the technical ability to manufacture the product.

59. Brand manufacturers can use the AG to capture some of the market share,

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[24] Food and Drug Administration: Decision Denying Citizen Petitions of Teva and Mylan, , Dkt. Nos. 2004P-00075/CP1 & 2004P-0261/CP1, at 11-12 (July 2, 2004)..

[25] *Id.* at 12.

[26] Kevin A. Hassett & Robert J. Shapiro, Sonecon, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals* 3 (2007), *available at* http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf (last accessed Feb. 14, 2020).

revenue, and profit that they would otherwise lose to the first-filer generic during its 180 days of exclusivity.

60. Brand manufacturers sometimes begin selling AGs before the first-filer generic enters the market in order to secure multi-year purchase contracts with direct purchasers and load the generic pipeline at the expense of the first-filer generic.

61. Competition from an AG substantially reduces drug prices and the revenues of the first-filer generic (especially during the 180-day exclusivity period).

62. A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[27]

63. The FTC similarly found that AGs capture a significant portion of sales, reducing the first-filer generic's revenues by about 50% on average.[28] The first-filer generic makes much less money when it faces competition from an AG because (i) the AG takes a large share of unit sales away from the first filer; and (ii) the presence of the AG causes prices, particularly generic prices, to decrease.

64. Authorized generics are therefore a significant source of price competition. In fact, they are the only potential source of generic price competition during the first-to-file generic manufacturer's 180-day exclusivity period. All drug industry participants recognize

[27] Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 HEALTH AFFAIRS 790, 796 (2007).

[28] FTC 2011 AG Study at 139.

this. PhRma recognizes it.[29] Generic companies recognize it.[30] Brand companies recognize it.[31]

C. Manipulation of the regulatory structure to impair competition.

65. The brand manufacturer of a pharmaceutical product that has no generic competition in the marketplace gets all of the profits on all of the unit sales. In this circumstance, brand manufacturers can usually sell their drug for far more than the marginal cost of production, generating profit margins in excess of 70% while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins is what economists call market power.

66. When a generic equivalent enters the market, however, it quickly captures 80% or more of the unit sales from the brand drug. When generic entry occurs, the brand manufacturer loses most of the unit sales and the generic manufacturer sells most of the units, but at drastically reduced prices--delivering enormous savings to drug purchasers. And when multiple generics compete in the market, that competition drives prices down to near the marginal cost of production. This competition ends the brand manufacturer's market power and delivers enormous savings to drug purchasers. Competition converts what formerly were

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[29] Brand industry group PhRma sponsored a study that concludes that the presence of an authorized generic causes generic prices to be more than 15% lower as compared to when there is no authorized generic. IMS Consulting, *Assessment of Authorized Generics in the U.S.* (2006), *available at* http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf (last accessed Feb. 14, 2020).

[30] One generic stated that "[d]ue to market share and pricing erosion at the hands of the authorized [generic], we estimate that the profits for the 'pure' generic during the exclusivity period could be reduced by approximately 60% in a typical scenario." *See* FTC 2011 AG Study at 81. Another generic manufacturer quantified the fiscal consequences of competing with an authorized generic and determined that the authorized generic reduced its first generic's revenues by *two-thirds*, or by approximately *$400 million*. Comment of Apotex Corp. in Support of Mylan Citizen Petition at 4, Docket No. 2004P-0075 (Mar. 24, 2004), *available at* https://web.archive.org/web/20041216115511/http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf (last accessed Mar. 2, 2020).

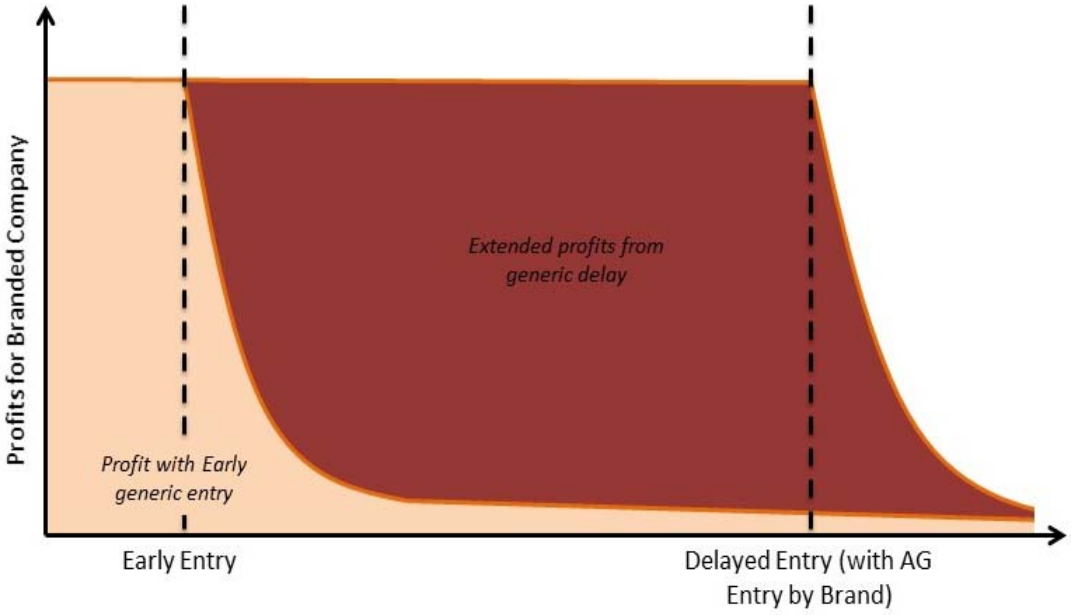
[31] Commenting on an FDA petition by drug manufacturer Teva Pharmaceuticals, Pfizer stated: "Teva's petition [to prevent the launch of an authorized generic] is a *flagrant effort to stifle price competition* – to Teva's benefit and the public's detriment." Comment of Pfizer at 6-7, Docket No. 2004P-0261 (June 23, 2004), *available at* https://web.archive.org/web/20050601041653/http://www.fda.gov/ohrms/dockets/dailys/04/June04/062904/04p-0261-cr00001-01-vol2.pdf (last accessed Mar. 2, 2020); Comment of Johnson & Johnson at 1, FDA Docket No. 2004P-0075 (May 11, 2004), *available at* https://web.archive.org/web/20041227172543/http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00002-vol1.pdf (last accessed Mar. 2, 2020).

excess profits into purchaser savings.

67. While brand manufacturers and first-filer generic manufacturers are typically marketplace competitors, they have a collective interest in preventing robust competition from several generic manufactures—competition that severely depresses prices—from breaking out. If they work together to prevent or delay such competition, they can keep the profit margins on all of the unit sales at 70% and split the resulting excess profits among themselves. In other words, by stifling competition, the brand manufacture and first-filer generic manufacturer can maintain high prices, protect their profits, and split between themselves the enormous savings that increased generic competition would have delivered to drug purchasers, such as plaintiffs.

68. Figure 1 compares the impact on a brand manufacturer's profits between (i) a situation where it settles a patent lawsuit on the merits (i.e., with only an agreed entry date and without a pay-off to the generic company); and (ii) a situation where it settles the lawsuit with a large, unjustified payment to the generic manufacturer. In the former situation, the agreed entry date for the generic is earlier and the brand manufacturer's profits are thus greatly reduced. In the latter situation, the agreed entry date is later and the brand manufacturer's profits increase significantly. Earlier entry may also occur if the generic manufacturer launches its product at risk (i.e., while the litigation is still pending) or prevails in the patent litigation and then launches its product.

Figure 1. Impact of Generic Delay on Brand Profits



69. For such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide between them the ill-gotten gains—the increased profit to the detriment of drug purchasers—that delayed competition makes possible. After all, the generic manufacturer will not refrain from competing if it does not share in the profit gains through some means. The means usually takes the form of pay-offs from the brand manufacturer, deals are often referred to as "pay-for-delay," "exclusion payment," or "reverse payment" agreements.

70. The brand manufacturer may choose to – unlawfully – pay off only the first filer, even if other generic manufacturers are also lined up to challenge the patents. The first filer's agreement to delay marketing its generic drug also prevents other generic manufacturers from marketing their products: none of the later-filers can enter until the first-filers 180-day exclusivity period has run.

71. Later ANDA filers have more modest financial expectations because they may have little or no expectation of any form of market exclusivity. By the time they enter the

market, there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been, or is on its way to being, commoditized.

72. But the decision to pay-off only the first-filer nonetheless has detrimental effects on market competition. In the absence of an anticompetitive agreement between the brand company and the first filer, later ANDA filers have procompetitive incentives. They are motivated to expend resources to challenge the brand manufacturer's patent(s) (knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

73. When an anticompetitive agreement with the first filer is already in place, however, pursuing the litigation to conclusion becomes less attractive to later filers. The later generic manufacturers know that the first filer is not leading the charge against the brand manufacturer's patent(s) (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive reverse payment agreement). The later generics will therefore have to bear the full brunt of the litigation costs themselves and, upon prevailing in the patent litigation, can expect to recoup less of those costs than the first-filers would have enjoyed because the later-filers will face more robust generic competition than a first-filer who enjoys an exclusivity period. Additionally, the first settlement between a brand and first-filer generic will often provide that in the event a later generic filer launches its generic before the delayed date agreed to by the brand and the first-filer, the first-filer is permitted to launch then as well – greatly reducing the incentive the later-filer would otherwise have to continue fighting to enter as soon as possible.

74. Thus, some later generics decide to simply give in to or join the conspiracy between the brand manufacturer and the first-filer generic and agree to drop their challenges to

the brand manufacturer's patent(s) and stay off the market until after entry by the first filer. This behavior furthers the harm to drug purchasers.

75. Pay-for-delay agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy expensive brands instead.

1. Brand drug manufacturers often create patent thickets to delay generic entry.

76. Brand drug manufacturers frequently engage in a predictable pattern of developing the patent portfolios for their profitable drugs.

77. The first patent or patents in a branded drug company's drug portfolio sometimes reflect a bona fide technological advancement, i.e., the development of a new drug compound that provides a therapeutic benefit.

78. After the original patent applications are filed, the company will continue research and development efforts to create a drug product that will be approved by the FDA and, in turn, allow them to generate profits by selling the drug in the U.S. market.

79. As these research and development efforts continue, so do patent applications, which typically reflect narrower modifications relating to more specific formulations, processes for creating, and methods of using the original drug discovery. By this point, there is significant "prior art" by way of the earlier patent applications. These later patents are therefore increasingly limited in terms of the scope that they may actually cover. In other words, a brand company can patent new features or methods of using a drug, only so long as they are not obvious in light of the growing body of prior art.

80. By now the brand company may have submitted its NDA to the FDA for approval. Upon approval, or the likelihood of approval, and if the drug is projected to be a

commercial success, the brand company will frequently ramp up its efforts to obtain additional patent protection. These later-applied-for-and-acquired patents frequently extend the ostensible period of patent exclusivity beyond the life of the original patents.

81. As a brand drug becomes a success, the incentive to obtain additional patent protection increases and brand drug manufacturers frequently intensify their efforts to do so. These patent applications typically result in patents (in light of the now extensive body of prior art) of still narrower coverage than the earlier-obtained patents. These narrower, later-obtained patents reflect, correspondingly, patents that are easier from the perspective of a would-be generic competitor to design or invent around by simply taking an approach that differs from those disclosed in the patents listed in the Orange Book by the brand drug manufacturer.

2. Reverse payments are a means to delay competition.

82. In connection with the resolution of patent litigation arising out of paragraph IV certifications, brand manufacturers pay off generic competitors in exchange for delaying their entry into the market. These agreements not to compete are known as "reverse payment agreements." Brand and generic manufacturers execute reverse payment agreements as purported settlements of patent infringement lawsuits that brand manufacturers file against generic manufacturers.

83. In a typical reverse payment agreement, the brand manufacturer pays a generic manufacturer to (i) delay or abandon market entry, and (ii) abandon the invalidity and unenforceability challenges to the brand manufacturer's patents. The brand manufacturer preserves its monopoly by paying some of its monopoly profits to the generic manufacturer, and the generic manufacturer agrees to delay marketing its product, allowing the brand

manufacturer to have an extended monopoly period.

84. The size of the payment is usually a proxy for assessing the patent merits. As the Supreme Court observed in *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013), "[t]he owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition." In other words, the Court went on, "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness . . . ."

85. In the 1990s, these agreements took the form of cash payments from the brand manufacturer to the generic competitor. As a result of regulatory scrutiny, congressional investigations, and class-action lawsuits, brand manufacturers and generic competitors have entered into increasingly elaborate agreements in attempts to hide the fundamentally anticompetitive character of these agreements and avoid liability.

***3.* No-AG agreements provide a means for brand and generic manufacturers to share the gains from conspiring.**

86. One form of pay-off, at issue here and which brand companies have increasingly used to disguise their reverse payments, is a "no-authorized generic" or "no-AG" agreement. With a no-AG agreement, the brand manufacturer agrees not to market an AG version of the brand drug for some period of time after the first generic enters the market in exchange for the first generic agreeing to a delayed entry date.

87. There is no statutory prohibition on a brand manufacturer launching an AG during the first-filer's 180-day ANDA exclusivity period. The Hatch-Waxman amendments' 180-day marketing period is "exclusive" only against other ANDA-based products, not as against the brand manufacturer's NDA-based AG.

88. Absent a no-AG promise, it almost always makes economic sense for the brand manufacturer to begin marketing an AG as soon as (or sometimes weeks or months before) the

first generic enters the marketplace.

89. But competition from an AG has a drastically negative effect on the first-filer generic's revenues. Competition from an AG typically cuts the first filer's revenues by more than half, as the competing generic takes a substantial volume of the unit sales and drives prices lower – delivering commensurate savings to drug purchasers.

90. To prevent an AG from causing this substantial loss of revenues and profits, a first-filer generic may be willing to delay its entry into the marketplace in return for the brand manufacturer's agreement to forgo competing with an AG during the exclusivity period. The additional monopoly profits that the brand manufacturer gains from the delayed onset of generic competition more than makes up for the profits it forgoes by temporarily not competing with its AG. The brand manufacturer gains from the delayed onset of generic competition; the first-filer gains from the absence of generic competition for the first 180 days of marketing.

91. Drug purchasers lose. The brand and first-filer's reciprocal pledges not to compete harm purchasers thrice over. *First*, the pact delays the first-filer's generic entry into the marketplace and thereby extends the time during which the more expensive brand is the only product on the market. *Second*, by delaying the first-filer's entry, the pact also delays the time when other, later, generics enter. *Finally*, the pact prevents the brand from marketing an AG during the 180-day exclusivity period (or beyond), reducing price competition during that period, particularly price competition that would otherwise occur between the first-filer's generic and the brand's AG.

92. For the first-filer, the difference between selling the only generic and competing against an AG for 180 days can amount to tens or even hundreds of millions of dollars, depending on the size of the brand's sales. A no-AG pledge thus has the same economic effect

as a pay-off made in cash, with even greater anticompetitive consequences as it removes a competitor. As explained by the then-Chairman of the FTC:

> Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, "if you go away for several years, I'll give you $200 million." Now, the brand might say to the generic, "if I launch an AG, you will be penalized $200 million, so why don't you go away for a few years and I won't launch an AG."[32]

Courts agree that no-AG agreements are a form of payment actionable under *Actavis* and are anticompetitive.[33]

93. For a first ANDA filer (like Par) for a brand drug with hundreds of millions in annual sales (like Amitiza), the difference between selling a generic without having to compete against another generic, whether AG or otherwise, amounts to tens, and in some instances, hundreds of million dollars. These economic realities are well known in the pharmaceutical industry. No-AG agreements thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

94. Figure 2 depicts what happens when a settlement agreement includes a no-AG promise. The red area shows the brand manufacturer's additional monopoly profits earned

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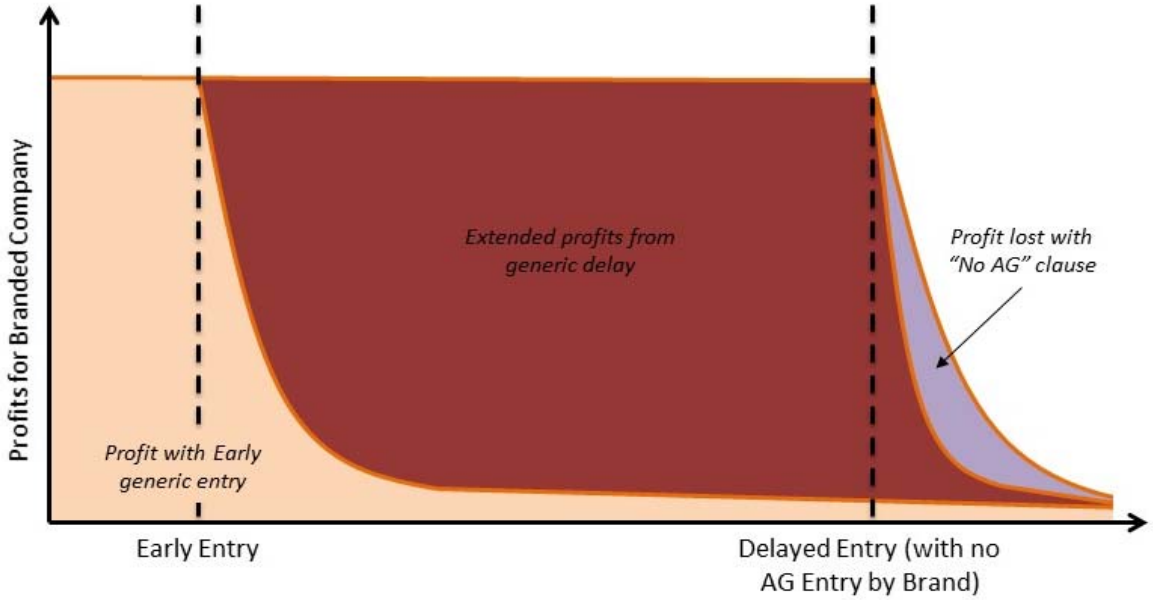
[32] "Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics," FTC (June 24, 2009), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authgenstatementleibowitz.pdf (last accessed Feb. 14, 2020).

[33] *See In re Loestrin 24 Fe Antitrust Litig.*, Nos. 14-2071, 15-1250, 2016 U.S. App. LEXIS 3049, at *25-26 (1st Cir. Feb. 22, 2016); *In re Opana ER Antitrust Litig.*, No. 14 C 10150, 2016 U.S. Dist. LEXIS 16700, at *23-25 (N.D. Ill. Feb. 10, 2016); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 242 (D. Conn. 2015); *United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069 (N.D. Cal. 2014); *In re Effexor XR Antitrust Litig.*, No. 11-cv-5479, 2014 U.S. Dist. LEXIS 142206, at *62 (D.N.J. Oct. 6, 2014); *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 709-10 (E.D. Pa. 2014); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

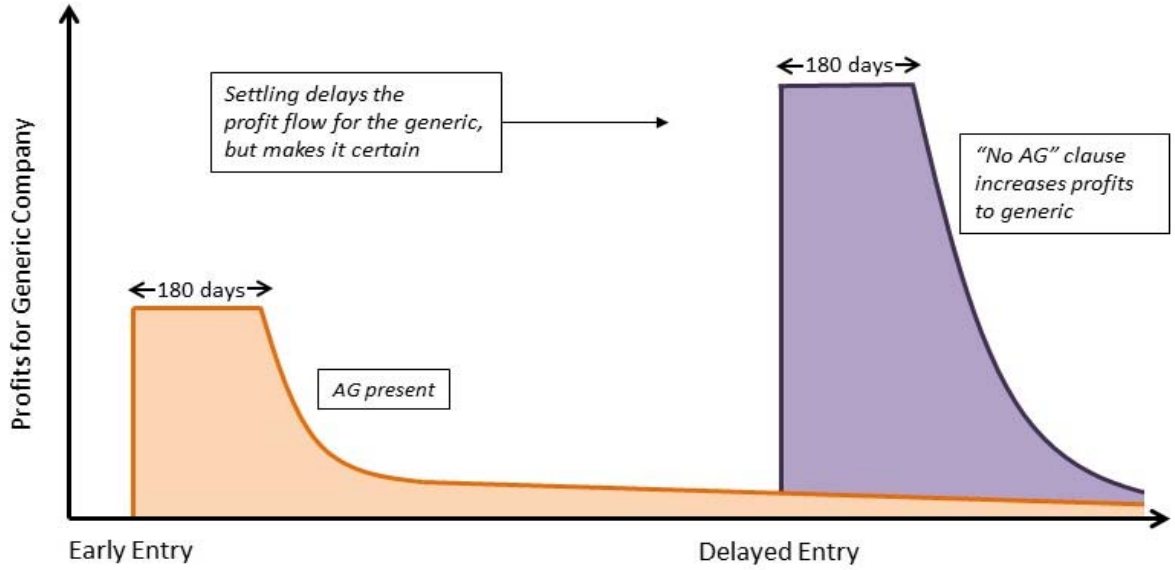
during the period of delay. The purple area shows the amount of monopoly profit the brand manufacturer gives up (i.e., shares with the generic).

Figure 2. Impact of No-AG Clause on Brand Profits



95. Figure 3 depicts the generic manufacturer's principal considerations in deciding whether to accept a settlement that includes a no-AG agreement. Without a settlement, the generic could enter earlier – either when the 30-month stay expires ("at risk") or when it wins the litigation. The generic manufacturer's profits (gross margins) would be high during the 180-day exclusivity period and then fall rapidly as additional generics enter. This profit flow is somewhat uncertain because (i) if the generic launches at risk, it could (theoretically) later be found to infringe a valid patent, and (ii) it is expected that the brand manufacturer will launch an authorized generic and capture approximately 50% of the generic's sales. With a no-AG promise, the profit flow occurs later but is more certain and is larger – roughly twice the size – because the generic manufacturer does not lose half of the market to the brand manufacturer's authorized generic and can charge a higher price.

Figure 3. Impact of No-AG Promise on Generic's Profits



96. Pay-offs by means of no-AG clauses usually exceed the value that the first-filer could have obtained *even if it had won* the patent infringement litigation. By settling the patent case in exchange for a no-AG payoff, the first-filer converts that critical six months (and in this case, possibly two years) into a period of *total* generic exclusivity that it was not otherwise entitled to, thus doubling its unit sales and making those sales at a higher price.

97. When a brand manufacturer agrees to a no-AG clause in exchange for delaying generic entry, the additional profits gained by causing delay to generic competition to achieve a longer monopoly period significantly outweigh any profit that could have been gained from selling an authorized generic. The bottom line is that the brand manufacturer gains a longer period of monopoly profits by delaying the onset of generic competition, and the generic first filer maintains higher generic sales and pricing during its 180-day exclusivity period. Thus, no-authorized generic agreements allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased

competition.

98. No-AG agreements need not be explicit to achieve their anticompetitive ends. According to the Federal Trade Commission ("FTC"), "[a]nother common form of possible compensation [to the settling generic] is an agreement containing a declining royalty structure, in which the generic's obligation to pay royalties is substantially reduced or eliminated if a brand company sells an AG," or more broadly upon the entry of any other generic product in the market. "[T]his type of provision does not explicitly preclude the brand from launching an AG, but it may achieve the same effect." As courts in this district have observed, an "explicit reservation . . . does not on its own preclude the existence of an implicit no-AG agreement." *Picone v. Shire*, No. 16-cv-12396, 2017 WL 4873506, at *9 (D. Mass. Oct. 20, 2017).

99. Because of the harm to purchasers caused by reverse payment agreements, reverse payment agreements, including no-AG agreements (however disguised), are anticompetitive and unlawful. As the First Circuit explained in considering a no-AG agreement, "antitrust scrutiny attaches not only to pure cash reverse payments, but to other forms of reverse payment that induce the generic to abandon a patent challenge, which unreasonably eliminates competition at the expense of consumers." *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 550 (1st Cir. 2016). Accordingly, if settling brand and generic drug companies agree that the brand "would not launch an AG so that [the generic] would be free from generic competition during its period of market exclusivity, then such an agreement would violate the Sherman Act." *In re Intuniv Antitrust Litig.*, 496 F. Supp. 3d 639, 671–72 (D. Mass. 2020).

V. FACTS

A. Sucampo develops Amitiza but hands commercialization rights and responsibilities to Takeda.

100. Sucampo Pharmaceuticals, Inc. developed Amitiza (lubiprostone) as a CIC-2 chloride channel activator in the 1990s and early 2000s for the treatment of constipation. Early on, before getting FDA approval, Sucampo agreed to have Takeda take responsibility for sales, marketing, and commercialization of Amitiza.

1. Before the Amitiza NDA was even submitted, Takeda becomes a licensee of the Amitiza patents and assumes responsibility for the marketing and commercialization of the drug in the U.S.

101. In 2004, with the expectation that Amitiza would be commercialized in North America, Takeda and Sucampo entered into a 16-year "exclusive" license, development, commercialization, and supply agreement concerning the marketing and sale of Sucampo's lubiprostone product in the U.S. and Canada, under which Sucampo was "primarily responsible for clinical development activities, . . . while Takeda is responsible for commercialization of Amitiza," including marketing and sale of the drug (the "North America Commercialization Agreement").

102. Under the agreement, Takeda paid a negotiated price for the Amitiza product, then sold it and paid a royalty back to Sucampo on the sale. For the sixteen-year term of the North America Commercialization Agreement, the royalty rate to be paid by Takeda was structured into three tiers based on annual net sales of Amitiza, ranging from 18-26%, resetting each year, putting the vast majority of Amitiza revenue in Takeda's hands throughout the relevant time period.

2. The agreement provided Takeda with an exclusive license to the Amitiza patents.

103. Takeda was integral to all Amitiza-related business and legal decisions under the

North America Commercialization Agreement, which provided for the creation of joint steering, development, manufacturing, and commercialization committees that met multiple times per year and required unanimous decision-making.[34]

104. In October 2014, Takeda and Sucampo amended their agreement to provide for an extension of its term beyond December 2020, after which time they would share evenly in the annual net sales revenue on branded Amitiza sales.

105. According to Sucampo's November 6, 2014 earnings call, Sucampo ceased all direct sales of Amitiza in the United States by the end of the 2014 calendar year, leaving Takeda solely responsible for the marketing and sale of the drug in the U.S. market throughout the entire class period.

3. The FDA approves the Amitiza NDA and the drug hits the U.S. market in 2006.

106. In March 2005, Takeda's collaboration partner Sucampo submitted NDA No. 21-908 to the FDA, seeking approval to manufacture, market and sell lubiprostone capsules in the United States, under the brand name Amitiza, for the treatment of adults with chronic idiopathic constipation (CIC). Amitiza has a dual mechanism of action, increasing intestinal fluid secretion while also stimulating recovery of mucosal barrier function.

107. On January 31, 2006, the FDA approved the manufacture, marketing, and sale of 24 mcg lubiprostone capsules to treat CIC in adults. Takeda began selling Amitiza in April 2006 and was responsible for most of the marketing, sales, and other commercialization efforts for Amitiza from that time forward.[35] As discussed above, Takeda retained the vast majority of revenues from sales of Amitiza.

[34] All decisions made by the committees were to be "evidenced in a writing signed by one of the members of the JSC from each of the Parties."

[35] Sucampo retained the right to co-promote and sell Amitiza.

108. On April 29, 2008, the FDA approved a second indication for Amitiza: treatment of irritable bowel syndrome with constipation (IBS-C) in women 18 years of age and older.

109. In July 2012, Takeda's collaboration partner Sucampo filed a supplemental new drug application with the FDA for a new, third indication: treatment of opioid-induced constipation (OIC). In April 2013, the FDA approved Amitiza for treatment of OIC in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation.

110. Each year, purchasers spend hundreds of millions of dollars on Amitiza. According to IQVIA, Amitiza sales were approximately $427 million for the 12 months ending on Sept. 30, 2020.

B. The patents ostensibly covering Amitiza and its uses were easy to design around.

111. Over time, seventeen patents ostensibly claiming aspects of Amitiza and its uses were filed for and/or obtained through assignment and listed in the FDA's Orange Book.

112. U.S. Patent No. 5,284,858 (the "'858 patent") covers prostaglandin E(1), from which lubiprostone—the active pharmaceutical compound in Amitiza—is derived. The '858 patent was the Amitiza drug substance, or compound, patent and the strongest patent in the Amitiza arsenal. It expired in July 2014.

113. The remaining sixteen patents listed in the Orange Book had expiration dates ranging from 2020 and 2027 and fall into three general categories.

114. Seven patents claim methods of treating various diseases by administering certain drug products. These patents are U.S. Patent Nos.:

7,064,148 (the "'148 patent");[36]
8,748,481 (the "'481 patent");[37]

[36] The '148 patent was never asserted against any of the generics in the litigations.

[37] The '481 patent was only asserted against Teva, Sun, and Zydus.

6,982,283 (the "'283 patent");[38]
7,795,312 (the "'312 patent");
6,414,016 (the "'016 patent");
8,071,613 (the "'613 patent"); and
8,097,653 (the "'653 patent").

115. Four patents claim drug product compositions. These patents are U.S. Patent Nos.:

8,088,934 (the "'934 patent");
6,583,174 (the "'174 patent");
7,417,067 (the "'067 patent"); and
8,097,649 (the "'649 patent").

116. Five patents claim simple pharmaceutical formulations of prostaglandins. These patents are U.S. Patent Nos.:

8,114,890 (the "'890 patent");[39]
8,779,187 (the "'187 patent");[40]
8,389,542 (the "'542 patent");
8,026,393 (the "'393 patent"); and
8,338,639 (the "'639 patent").

117. The weak nature of the patents and their claims meant that none of these additional patents stood as legitimate impediments to generic competition, though the listing of them in the Orange Book meant that every potential generic competitor would have to address them.

C. Par files the first ANDA for generic Amitiza; Takeda and Sucampo immediately sue Par, triggering the 30-month stay of approval of the first potential generic competitor.

118. In February 2010, Par submitted an ANDA to the FDA seeking approval to manufacture, market, and sell a generic version of Amitiza in 8 and 24 mcg strengths once the

[38] The '283 patent was only asserted against Teva and Amneal.

[39] The '890 patent was never asserted against any of the generics in the litigations.

[40] The '187 patent was only asserted against Sun and Zydus.

'858 drug substance patent expired.[41]

119. Par later either amended its existing ANDA or filed a new ANDA, seeking approval to manufacture, market, and sell a generic version of Amitiza in 8 and 24 mcg strengths. The FDA accepted this application for filing on August 20, 2012.

120. As the first generic to submit a substantially complete ANDA for lubiprostone, Par was potentially eligible for 180-days of ANDA exclusivity for generic Amitiza when it received approval, meaning no other ANDA generic could be sold during that time.

121. On December 26, 2012, Par sent a Paragraph IV notice letter to Sucampo, representing it had filed an ANDA seeking approval to manufacture, market, and sell a generic version of Amitiza following expiration of the '858 drug substance patent in 2014. On information and belief, Par's notice letter claimed that all of the other twelve patents then listed in the Orange Book as covering Amitiza were invalid or would not be infringed by Par's generic product.

122. On January 24, 2013, Par sent a second Paragraph IV notice letter, certifying that the newly issued '639 patent was invalid, unenforceable, and/or not infringed by Par's generic Amitiza product.

123. On February 7, 2013, Takeda and Sucampo sued Par in the United States District Court for the District of Delaware for alleged infringement of claims of six method of use and gel cap formulation patents: the '016, '613, '312, '393, '653, and '639 patents.

124. On May 7, 2013, Par sent a third Paragraph IV notice letter certifying that the newly issued '542 patent was invalid, unenforceable, and/or not infringed by Par's generic

[41] Though Anchen was the entity that submitted the ANDA, Par acquired Anchen, and all the rights to the lubiprostone ANDA, in November 2011. The plaintiffs thus refer to this entity as Par throughout.

Amitiza product.

125. On July 3, 2013, Takeda and Sucampo amended their complaint to allege infringement of claims of the '542 patent.

D. Sucampo, in collaboration with Takeda, files—and the FDA summarily rejects—a baseless Citizen Petition with the FDA seeking more stringent requirements for approval of a generic Amitiza ANDA product.

126. On January 17, 2014, Sucampo, with Takeda's knowledge and approval, submitted a Citizen Petition to the FDA requesting that the FDA "revise its existing proposed criteria for how to demonstrate bioequivalence for lubiprostone capsules as set forth in this petition," and "apply such revised criteria to any abbreviated new drug application (ANDA) that relies upon the new drug application (NDA) for AMITIZA® (lubiprostone) capsules (NDA 21-908) as the reference listed drug."[42]

127. To those ends, Sucampo argued that the FDA should require of generic Amitiza ANDA filers (1) "a clinical endpoint study in the treatment of irritable bowel syndrome with constipation"; (2) "a clinical endpoint study in opioid-induced constipation"; (3) "a demonstration of equivalent safety"; and (4) "the chronic idiopathic constipation clinical endpoint study to use frequency of spontaneous bowel movements as its endpoint."

128. On July 17, 2015, the FDA denied the Citizen Petition.[43] In doing so, the FDA stated that the Citizen Petition's request for clinical data demonstrating an equivalent safety profile was based on the "incorrect" premise that different lubiprostone products may have different safety profiles. The FDA stated there was no "reason[] to question" the "decades of scientific data on the variability of product characteristics" "or the statistical standards used to ensure meaningful bioequivalence results." Of generic Amitiza products that are qualitatively

[42] Citizen Petition Denial Response from FDA CDER to Sucampo Pharma Americas, LLC, Doc. FDA-2014-0144-0003, (July 17, 2015), *available at* https://www.regulations.gov/document/FDA-2014-P-0144-0001.

[43] *Id.*

and quantitatively similar to the reference listed drug, the FDA said the notion that the generic product could have a "different safety profile from Amitiza is speculative and *not supported by any scientific basis*."

129. The Citizen Petition was a meritless sham, filed with the intent to use a government process to delay ANDA approval and market entry of generic versions of Amitiza in order to artificially protect and extend Takeda's and Sucampo's monopoly over the drug.

E. Takeda and Sucampo enter into a reverse payment agreement with Par, sharing monopoly profits with Par in exchange for Par's agreement to stay off the market until 2021.

130. On or about September 30, 2014, Takeda and its collaboration partner Sucampo settled their patent litigation with Par, acknowledging to the district court on October 9, 2014 the "significant risk" of continuing the patent infringement action.

131. Under the Par Settlement Agreement, Par agreed to delay selling a generic version of Amitiza until January 1, 2021 (or earlier under certain circumstances). Once it entered, Par would pay a declining royalty on its gross profits from the sales of its generic Amitiza based on the number of other generic entrants; specifically, Par would pay (1) 50% as the only generic on the market, (2) 15% with one other generic on the market (whether an authorized generic ("AG") or a third-party ANDA generic), and (3) no royalty with two or more additional generics.

132. The Par Settlement Agreement gave Par the option to market AG Amitiza as of January 1, 2021 instead of manufacturing and selling Par's own generic Amitiza under its ANDA. The Par Settlement Agreement's terms—and specifically the 50% profit split/royalty—would apply whether Par sold AG Amitiza or its own ANDA generic Amitiza.

133. While Takeda and its collaboration partner Sucampo technically reserved the ability to launch their own authorized generic product, the economics created by the structure

of the agreement ensured that both the brand companies and Par would be better off if Takeda never launched an AG to compete with Par's launch.[44] Whether Par marketed its own ANDA generic Amitiza or an AG Amitiza provided by Takeda, all of the defendants would be better off with no additional generic competition.

134. AB-rated generics are commodity products; they compete on price. The more AB-rated generics on the market, the lower their prices. The greatest downward pressure on generic prices comes when a second generic enters. Before then, the sole generic typically prices at a small discount to the brand. With additional entrants, the discount increases, reducing prices for purchasers and profits for manufacturers.

135. The Par Settlement Agreement made it far more profitable for both Takeda and Par for Par to be the sole generic on the market—whether as the sole AG or through its own ANDA. Though Par's royalty rate would drop from 50% to 15% if another generic or AG were on the market, the higher royalty rate was still more profitable for Par because, in the absence of other generic or AG competition, Par would realize much higher unit sales at much higher prices. Similarly, the Par Settlement Agreement made it far more profitable for Takeda not to launch an AG, since it would earn more by not launching an AG and instead receiving a larger royalty on Par's sales at a higher price as the sole generic on the market, than it would by launching an AG that would compete with Par's ANDA product, drive prices down, and result in much lower overall revenues, including a lower royalty.

136. Under normal, lawful circumstances, brand companies routinely license third parties to market and sell AGs to compete with ANDA generics, as a means to recoup some of the sales that the ANDA generic(s) will take. Indeed, on at least eight occasions, Takeda has

[44] Takeda has repeatedly launched authorized generic products through third parties. Its refrain from doing so in this instance is strong evidence that the Par Settlement Agreement served as a no-AG agreement to delay Par's entry.

done just this for its own drugs.

137. The industry standard for AG licenses outside of a pay-for-delay settlement has the generic company launching the AG paying 90% of its profits to the brand company. The Par Settlement Agreement required only a 50% royalty. This far-below-market rate royalty was an effective large payment to Par, designed to get Par to agree to a long delay in generic entry for Takeda's benefit, and to agree not to challenge the weak patents on Amitiza.

1. Amitiza capsule sales were approximately $ 427 million for the 12 months ending on Sept. 30, 2020.

138. Absent the anticompetitive agreement, and using industry standards, if Par launched its ANDA product, and the brand launched an AG, the two generics would be priced at approximately 60% of the brand, they together would take 90% of all lubiprostone unit sales, and Par would make half of the generic sales. Par's revenues during the first 180 days (when other ANDA generics are foreclosed from the market by FDA regulation) would be ($ 427 million) * (0.5 year) * (0.6 percentage of the brand price) * (0.9 generic penetration) * (0.5 of the generic market) = $ 57.6 million. And Takeda would make the same amount if it launched an AG, $ 57.6 million.

139. Under the Par Settlement Agreement, both Par and Takeda will make a lot more revenue due to their effective mutual agreement to monopolize the generic market. If Par marketed the AG (as it elected to do) and Takeda did not launch another AG (which, in fact, Takeda didn't), using industry standards, Par's AG would be priced at approximately 90% of the brand, would take 90% of all lubiprostone unit sales, and 100% of all generic sales. Par's revenues during the first 180 days would be ($ 427 million) * (0.5 year) * (0.9 percentage of the brand price) * (0.9 generic penetration) * (1 sole entrant in the generic market) = $ 173 million. Par would pay a 50% royalty to the brand and retain the other 50% = $ 86.5 million.

140. The payment to Par is the difference between its revenues under the Par

Settlement Agreement ($ 86.5 million), and what it would have received absent any anticompetitive agreement ($ 57.6 million), which is $ 28.9 million. This difference of $ 28.9 million is an unlawful reverse payment from Takeda to Par *just during the first 180 days*. And Takeda's reverse payments to Par continue for four times that long: two full years.

141. The same result would occur under the Par Settlement Agreement if Par elected to come to market with its ANDA generic Amitiza rather than as the AG.

142. Either way, the deal was structured to ensure the brand would not launch another generic to compete with Par. Doing so would both decrease the prices that the generics could charge (thus reducing the universe of potential profits) and decrease the amount of the royalty to be paid by Par to the brand. With an AG on the market, instead of making $ 86.5 million each during those first 180 days, Par's revenues would be ($ 427 million) * (0.5 year) * (0.6 percentage of the brand price) * (0.9 generic penetration) * (0.5 of the generic market) * (.85 retained profit after royalty) = $ 49 million.

143. Takeda's revenues for an AG during that time would be ($ 427 million) * (0.5 year) * (0.6 percentage of the brand price) * (0.9 generic penetration) * (0.5 of the generic market) * (1.15 full AG profit plus 15% royalty from Par) = $ 66.3 million, far less than the $ 86.5 million that Takeda receives under the terms of the Par Settlement Agreement.

144. Therefore, under the Par Settlement Agreement, Takeda will not launch an AG, because it earns more by not launching an AG ($ 86.5 million) than by launching an AG ($ 66.3 million).

145. If Takeda launched an AG, putting two generics on the market, Par would pay a smaller royalty on smaller profits, and the foregone royalty payments would cost Takeda more than it would gain in revenues from AG sales. No economically rational actor would take that option.

146. Takeda, Sucampo, and Par all knew that while Par had the choice to either market the AG or launch its own ANDA product, Takeda would not launch its own AG in either case and therefore, no matter what Par chose, there would only be one generic on the market regardless of what purported rights any party retained. That is, the Par Settlement Agreement was at least a de facto no-AG agreement, since it provided for a single generic to have the entire generic market in return for delayed generic entry and a share of the revenues.

147. The value of this de facto no-AG agreement to Par just during the first 180 days of its generic entry is at least $ 28.9 million, the difference between Par's likely revenue under the Par Settlement Agreement and Par's likely revenue absent the agreement.

148. This effective payment to Par of at least $ 28.9 million induced Par to accept a delay of its generic entry until January 2021 and drop its challenge to the vulnerable Amitiza patents.

149. This effective payment of $ 28.9 million far exceeds any reasonable estimate of litigation expenses that Takeda and Sucampo would have saved by settling the litigation with Par.

F. The no AG deal to Par and subsequent settlements allowing for further generic entry in January 2023 reflect a 2-year period of de facto exclusivity for Par, making the payment even larger.

150. Takeda ultimately settled litigation with five other potential generic manufacturers: Dr. Reddy's, Amneal, Teva, Sun, and Zydus. Each agreement set the entry date for those generics as January 1, 2023, meaning that the Par-marketed AG will be the only generic on the market for two years.

151. Assuming roughly constant Amitiza sales and 90% generic penetration at 90% of the brand price, Par's estimated revenues over that two-year period would be ($ 427 million) * (2 years) * (0.9 generic penetration) * (0.9 percentage of the brand price) = $ 692 million. After

paying a 50% royalty, Par will retain $ 346 million.

152. Absent any anticompetitive agreements, Par and Takeda would each have earned $ 57.6 million in the first 180 days of generic entry, as explained above. After the first 180 days, there would have been a Takeda AG, a Par ANDA generic, and five other ANDA generics all sharing the 90% generic share of the market at 10% of the brand price. Takeda, Par, and each of the other generic companies would each earn ($ 427 million) * (1.5 years) * (0.9 generic penetration) * (0.1 percentage of the brand price) * (0.143 each generic's share of the market) = $ 8.2 million over that period. Par and Takeda's total generic revenues for that two-year period would have been only ($ 57.6 million) + ($ 8.2 million) = $ 65.8 million each.

153. The value of two years of generic exclusivity to Par is the difference between the revenue that it will receive during the two years after paying a 50% royalty ($ 346 million) and what it would have received absent any anticompetitive agreements ($ 57.6 million for the first 180 days, then $ 8.2 million for the next 1.5 years, for a total of $ 65.8 million), which is $ 280 million.

154. Takeda's increased revenue from the two years of Par's generic exclusivity is the difference between the amount that Takeda will receive over those two years in royalty payments from Par ($ 346 million), and what Takeda would have received in revenue absent any anticompetitive agreements ($ 65.8 million), which is $ 280 million.

155. The value of these unlawful reverse payments far exceed what Par would have earned had it prevailed in the patent litigation, and these payments induced Par to accept a delay of its generic entry until January 2021 and drop its challenge to the vulnerable Amitiza patents.

156. In the absence of Takeda's unlawful payment to Par, either Par would have prevailed in the infringement litigation and come to market in January 2016 or earlier, or the

parties would have negotiated an earlier, payment-free entry date based upon an assessment of the strengths and weaknesses of the patents.

1. Dr. Reddy's settles and receives a license to enter with its generic Amitiza in January 2023.

157. In or about late summer or early fall of 2014, Dr. Reddy's submitted ANDA No. 206994 to the FDA seeking approval to manufacture, market, and sell a generic version of Amitiza in 8 and 24 mcg strengths.

158. On October 3, 2014, Dr. Reddy's served a Paragraph IV certification notice letter regarding its generic Amitiza ANDA. In its Paragraph IV certification, Dr. Reddy's asserted that all but the '283 patent, which claims a method of treating drug-induced (opioid) constipation—applicable to just one of the three indications for which Amitiza had been approved—were invalid, unenforceable, and/or not infringed. The '283 posed no impediment to Dr. Reddy's coming to market with its generic Amitiza product to treat either CIC or IBS-C.

159. Dr. Reddy's asserted that the following patents ostensibly covering Amitiza were invalid, unenforceable, or would not be infringed by Dr. Reddy's generic Amitiza ANDA product: the '016, '174, '148, '067, '393, '613, '934, '649, '890, '639, '481, '187, '312, '653, and the '542 patents.

160. In response to Dr. Reddy's Paragraph IV notice letter, on or about November 10, 2014, Sucampo sent its own letter bearing the subject line "Dr. Reddy's ANDA No. 206994 Sucampo's Covenant Not to Sue," in which covenanted not to sue on seven of the fifteen patents included in Dr. Reddy's Paragraph IV notice letter:

> In reliance on Dr. Reddy's representations in its October 1, 2014 letter and accompanying materials, Sucampo, on behalf of itself, and its exclusive licensee, Takeda Pharmaceutical Company Limited and its sublicensees Takeda Pharmaceutical USA, Inc. and Takeda Pharmaceuticals America, Inc., agrees and covenants not to sue Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., or any of their customers, for infringement of

> any claim of the '174, '148, '067, '934, '649, '890, and '187 patents with respect to ANDA No. 206994, or the past, present, or future manufacture, use, sale, offer for sale, or import of the products described in that ANDA.

161. On November 12, 2014, Sucampo and Takeda sued Dr. Reddy's for patent infringement in the United States District Court for the District of New Jersey, asserting the same seven patents they had asserted against Par before settling with it: the '016, '613, '312, '393, '653, '639, and '542 patents.

162. While Dr. Reddy's also filed a Paragraph IV certification as to the '481 patent, Sucampo and Takeda did not assert it against Dr. Reddy's.[45]

163. Accordingly, the same seven patents at issue in the Par litigation that, because of their vulnerability, resulted in a large, unjustified payment to Par to delay its entry, were the only patents at issue in the Dr. Reddy's action.

164. On November 9, 2016, before claim construction briefing had concluded and following a court-mediated settlement conference, the parties informed the district court that they had reached a settlement agreement, under which Dr. Reddy's would delay manufacture, marketing, and sale of its generic Amitiza until "January 1, 2023 or at such earlier date as may be permitted by the resolution to which the Parties have agreed."

165. Dr. Reddy's will also have the option to market another AG Amitiza instead of its own ANDA Amitiza.

166. The district court entered the parties' proposed Consent Judgment and Order on November 21, 2016. In the Consent Judgment and Order, Sucampo and Takeda "acknowledge[d] there is a significant risk" associated with their continued prosecution of the litigation.

[45] The '283 patent was also not asserted against Dr. Reddy's.

2. From 2017 to 2020, Takeda settles with four additional potential generic competitors, all with a January 2023 entry date.

167. On March 2, 2017, Amneal Pharmaceuticals LLC notified the brand in a Paragraph IV certification notice letter that it had filed generic Amitiza ANDA No. 209450 and asserted that many, if not all, of the Orange-Book-listed Amitiza patents were invalid, unenforceable, and/or not infringed.

168. On April 13, 2017, Takeda and Sucampo filed suit against Amneal in the United States District Court for the District of New Jersey alleging infringement of the '283, '653, '542, '393, and '639 patents.

169. On August 14, 2017, Teva sent the brand a Paragraph IV certification notice letter about its generic Amitiza ANDA No. 209920 and asserted that many, if not all, of the Orange-Book-listed Amitiza patents were invalid, unenforceable, and/or not infringed.

170. On September 25, 2017, Takeda and Sucampo filed suit against Teva in the United States District Court for the District of New Jersey alleging infringement of the '016, '613, '312, '283, '653, '542, '393, '639, and '481 patents.

a. Amneal and Teva settle.

171. On August 17, 2018, before claim construction proceedings even began, Amneal and the brand informed the district court that the parties had reached a settlement agreement, under which Amneal would delay manufacture, marketing, and sale of its generic version of Amitiza until "January 1, 2023 or at such earlier date as may be permitted by the resolution to which the Parties have agreed."

172. Two weeks later, on August 30, 2018, Teva and the brand informed the district court that the parties had reached a settlement agreement, under which Teva would delay manufacture, marketing, and sale of its generic version of Amitiza until "January 1, 2023 or at

such earlier date as may be permitted by the resolution to which the Parties have agreed."

173. The district court entered Consent Judgment and Orders on September 19, 2018 in both the Amneal and Teva cases. In both orders, Takeda and Sucampo "acknowledge[d] there is a significant risk" associated with their continued prosecution of the litigation.

174. Takeda and Sucampo settled each of the six patent infringement suits they brought against the generic Amitiza ANDA filers within the 30-month stay against approval of their respective ANDA products. As Par would ultimately enter the market as an AG (though that fact was concealed from the plaintiffs for years), it had no incentive to pursue its ANDA. As for the other generics, with their entry delayed until 2023 as a result of the Par no-AG deal, they deprioritized the pursuit of the approval of their ANDAs.

175. On June 19, 2019, the FDA tentatively approved Amneal's generic Amitiza ANDA.

b. Takeda and Sucampo sue and quickly settle with Sun and Zydus.

176. On September 18, 2018, Sun Ltd sent the brand a Paragraph IV certification notice letter about generic Amitiza ANDA No. 212292 and asserted that many, if not all, of the Orange-Book-listed Amitiza patents were invalid, unenforceable, and/or not infringed.

177. On October 30, 2018, Takeda and Sucampo filed suit against Sun in the United States District Court for the District of New Jersey alleging infringement of the '312, '653, '542, '393, '639, '187, and '481 patents.

178. On September 18, 2018, Zydus Pharmaceuticals (USA) Inc. sent the brand a Paragraph IV certification notice letter about generic Amitiza ANDA No. 214131 and asserted that many, if not all, of the Orange-Book-listed Amitiza patents were invalid, unenforceable, and/or not infringed.

179. On January 28, 2020, Takeda and Sucampo filed suit against Zydus in the United

States District Court for the District of New Jersey alleging infringement of the '312, '393, '639, '187, and '481 patents.

180. On July 1, 2020, before any substantive proceedings occurred, including claim construction, the parties to the Sun litigation informed the district court that they had reached a settlement agreement, under which Sun would delay manufacture, marketing, and sale of its generic version of Amitiza until "January 1, 2023 or at such earlier date as may be permitted by the resolution to which the Parties have agreed."

181. The district court entered the parties' proposed Consent Judgement and Order of Permanent Injunction the same day. In the Consent Judgment and Order of Permanent Injunction, Takeda and Sucampo "acknowledge[d] there is a significant risk" associated with their continued prosecution of the litigation.

182. A few months later, on November 12, 2020 and likewise before any substantive proceedings occurred, including claim construction, the parties to the Zydus litigation informed the district court that they had reached a settlement agreement, under which Zydus would delay manufacture, market, and sale of its generic version of Amitiza until "January 1, 2023 or at such earlier date as may be permitted by the resolution to which the Parties have agreed."

183. The district court entered the parties' proposed Consent Judgement and Order of Permanent Injunction the next day. In the Consent Judgment and Order of Permanent Injunction, as it had in every one of the litigations, Takeda and Sucampo "acknowledge[d] there is a significant risk" associated with their continued prosecution of the litigation.

G. None of the patents ultimately asserted by Takeda and Sucampo posed an impediment to generic entry.

184. Each of the six generic Amitiza ANDA filers ultimately sued by Takeda and Sucampo detailed in legally-mandated notification letters why their ANDA products would not infringe any of Sucampo's patents. While these notification letters are not publicly available,

their existence is not in doubt, and their contents will provide compelling evidence—along with the quick settlements doled out by Takeda and Sucampo providing for entry dates years before the expiry of their ostensible patent protection—that none of the asserted patents would have prevented generic entry upon expiry of the '858 drug substance patent in 2014.

185. Additionally, in each of the six patent infringement actions the brand filed, the generic drug manufacturer answered and counter-claimed, asserting that each of the patents asserted were invalid, unenforceable, and/or not infringed and, accordingly, that none are impediments to the generic Amitiza ANDA products.

186. A number of the Amitiza patents were never asserted.

187. Takeda knew the four later-issued drug product composition patents (the '934, '174, '067, and '649 patents) could never have survived in court, given that their claims are not patentably distinct from the claims of the '858 patent (or indeed from each other).[46] That they were never asserted against any of the six generics against whom the Amitiza patents were litigated underscores Takeda's and Sucampo's view that none of these patents posed any impediment to any generic Amitiza ANDA filer.

188. A handful of the method of use and composition patents were either never asserted against any of the six generics, or never asserted against the first two filers, Par and Dr. Reddy's. Neither the '148 nor the '890 patents were asserted against any generic Amitiza ANDA filer. The brand also did not assert the '481, '283, or '187 patents against either Par or Dr. Reddy's, underscoring that the patents posed no impediment to generic Amitiza market

[46] The claim construction order issued by Chief Judge Sleet in the District of Delaware litigation against Par put to rest any argument that the bicyclic compounds claimed in these four patents differ from the monocyclic compounds claimed in the '858 patent. *See* Order Construing the Terms of U.S. Patent Nos. 7,795,312, 8,026,393, 8,338,639, 8,097,653, and 8,389,542, C.A. No. 13-cv-202-GMS (D. Del. May 5, 2014) [ECF No. 96] (ordering "that the claimed 13,14-dihydro-15-keto-16,16-difluoro prostaglandin E1 compounds can exist in either monocyclic or bicyclic form, as well as mixtures of both forms.").

entry.

189. In all, ten patents were ultimately asserted across the six patent cases against generic Amitiza ANDA filers—the '016 patent, the '613 patent, the '653 patent, the '542 patent, the '312 patent, the '481 patent, the '283 patent, the '393 patent, the '639 patent, and the '187 patent.

190. Of the seven (of sixteen) Orange Book-listed patents asserted against Par and Dr. Reddy's, none claimed the drug substance lubiprostone by itself. Four claimed methods of treating various diseases by administering certain drug products and three claimed simple formulations of prostaglandins.

191. Method of treatment patents, like all patents, must claim novel and non-obvious improvements over the prior art to be upheld in court.[47] All four method of treatment patents asserted against Par and Dr. Reddy's claimed methods of using the prostaglandin compounds to treat constipation and/or irritable bowel syndrome. On information and belief, the use of prostaglandin compounds to treat constipation and irritable bowel syndrome was well known in the art at least as early as 1987, many years prior to the earliest filed of the method of treatment patents asserted against Par and Dr. Reddy's. Accordingly, all the methods of treatment patents would have been found invalid, unenforceable, and/or not infringed by the manufacture, use or sale of the generics' ANDA products, and therefore would not have impeded Par's or Dr. Reddy's market entry for generic Amitiza absent the 30-month stay.

192. The three formulation patents would likewise have been held invalid, unenforceable, and/or not infringed by the manufacture, use or sale of the generics' ANDA products. Each of them claims formulations of prostaglandin compounds, using known excipients to formulate a pharmaceutical dosage form (at least two of which are gel cap

[47] 35 U.S.C. §§ 102, 103.

formulations). For example, the gel cap has been known in the art for nearly 200 years; none of the claims would have met the standard of nonobviousness to prevent Par's or Dr. Reddy's market entry for generic Amitiza absent the 30-month stay.

193. In short, the patents that Takeda and Sucampo actually sued on were vulnerable, easily-designed around formulation and method of use patents. The asserted patents posed no real barrier to entry, outside of the 30-month stay against ANDA product approval that sprang from each litigation. Takeda and Sucampo covenanted not to sue on at least six patents and then quickly settled each successive infringement suit they brought, lopping years off the life of their patents but still achieving significant generic delay, recognizing that the Amitiza patents would not be legitimate barriers to entry.

H. The value of the infringement settlements to Takeda and Sucampo is substantial.

194. Sucampo publicly announced the settlement with Par in a press release issued and 8-K filed around the close of business on Oct. 9, 2014. On Oct. 10, 2014, Sucampo's stock price increased by an adjusted return of +11.5%, one of the two largest stock price increases Sucampo experienced over the preceding four months, and reflecting that Sucampo's investors understood that the Par Settlement Agreement would be highly profitable for Sucampo. And what was profitable for Sucampo would be far more so for Takeda, which received the vast majority of the revenues from Amitiza.

195. Through the Par Settlement Agreement, Takeda postponed generic competition for several years, and Takeda sold brand Amitiza at monopoly prices during those years without any danger of losing most of the market to cheaper generics.

196. Earlier generic competition, and more of it, could have occurred lawfully in a number of ways. If, for example, Par had won the patent litigation as of January 2016, Par's generic Amitiza and an AG Amitiza would have launched thereafter, five years earlier than the

delayed single generic January 2021 entry and six and a half years earlier than the January 2023 delayed multi-generic entry.

197. The delay achieved by the no-AG deal with Par and the later settlements with the remaining generics meant billions more in sales of Amitiza to Takeda.

I. Par comes to market with AG Amitiza, and was and is the only generic Amitiza product available.

198. On January 4, 2021, Endo International plc, Par's corporate parent, announced that Par had "begun shipping the first authorized generic versions of [...] Amitiza (lubiprostone) 8mcg and 24 mcg capsules," confirming Par's election to proceed as the AG, rather than under its own ANDA.

199. Takeda and Sucampo have not launched their own AG and instead are sharing in the monopoly profits generated by the Par-marketed AG being the only generic on the market.

VI. CLASS ALLEGATIONS

200. Plaintiffs bring this action as a class action under Rules 23(a) and (b)(3) of the Federal Rule of Civil Procedure on behalf of themselves and as representatives of a class defined as follows:

> All persons and entities in the United States and its territories that directly purchased Amitiza, authorized generic Amitiza, and/or generic Amitiza in any form, from January 1, 2016 until the effects of defendants' conduct cease.

201. Excluded from the class are Takeda and Par and any of their officers, directors, management, employees, parents, subsidiaries, and affiliates.

202. Also excluded from the class are the government of the United States and all agencies thereof, and all state and local governments and all agencies thereof.

203. The class seeks damages for at least the four years preceding the date this

complaint was filed.

204. Members of the class are so numerous and geographically dispersed that joinder of all members is impracticable. The plaintiffs believe that the class is numerous and widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The class is readily identifiable from information and records in the defendants' possession.

205. The direct purchaser plaintiffs' claims are typical of the claims of the members of the class. The direct purchaser plaintiffs and all members of the direct purchaser class were damaged by the same wrongful conduct of the defendants – i.e., as a result of the defendants' conduct, they paid artificially inflated prices for Amitiza, AG Amitiza, and/or generic Amitiza.

206. The direct purchaser plaintiffs will fairly and adequately protect and represent the interests of the class. The interests of the direct purchaser plaintiffs are coincident with, and not antagonistic to, those of the other members of the class.

207. Counsel who represent the direct purchaser plaintiffs are experienced in the prosecution of antitrust class action litigation, and have particular experience with antitrust class action litigations involving pharmaceutical products.

208. Questions of law and fact common to the members of the class predominate over questions that may affect only individual class members, because the defendants have acted on grounds generally applicable to the entire class, thereby making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in the defendants' wrongful conduct.

209. Questions of law and fact common to the class include:

a. Whether the defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;

b. Whether there exist any legitimate procompetitive reasons for some or all of the defendants' conduct;

c. To the extent such justifications exist, whether there were less restrictive means of achieving them;

d. Whether direct proof of the defendants' monopoly power is available and, if so, whether it is sufficient to prove the defendants' monopoly power without the need to define the relevant market;

e. Whether the defendants' scheme, in whole or in part, has substantially affected interstate commerce;

f. Whether the defendants' unlawful agreement, in whole or in part, caused antitrust injury through overcharges to the business or property of the plaintiffs and the members of the class;

g. Whether defendants conspired to delay generic competition for Amitiza;

h. Whether the Par Settlement Agreement was a reverse payment agreement;

i. Whether, pursuant to the Par Settlement Agreement, Takeda and Sucampo's effective promise not to compete against Par's generic product constituted a payment;

j. Whether Takeda's agreement with Par was necessary to yield some cognizable, non-pretextual procompetitive benefit;

k. Whether Takeda's compensation to Par was large and unexplained;

l. Whether the Par Settlement Agreement created a bottleneck to further delay generic competition for Takeda and Par;

m. Whether the reverse payment harmed competition;

n. Whether Takeda's settlements with Dr. Reddy's, Amneal, Teva, Sun, and Zydus with a January 1, 2023 entry date were intended to further delay full generic competition;

o. Whether, before January 1, 2021, Takeda possessed the ability to control prices and/or exclude competition for Amitiza;

p. Whether, from January 1, 2021 through December 31, 2022, Takeda and Par have possessed and will continue to possess the ability to control prices and/or exclude competition for Amitiza;

q. Whether the defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Amitiza or in causing some amount of delay in the market entry of multiple competing AB-rated generic Amitiza products;

r. Determination of a reasonable estimate of the amount of delay the defendants' unlawful monopolistic conduct caused, and;

s. The quantum of overcharges paid by the class in the aggregate.

210. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

211. The direct purchaser plaintiffs know of no special difficulty to be encountered in litigating this action that would preclude its maintenance as a class action.

VII. MARKET POWER AND RELEVANT MARKET

212. The pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Amitiza, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy, while the patient (and in most cases his or her insurer) has the obligation to pay for the product.

213. Brand manufacturers, including Takeda, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are largely

insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

214. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the cross-price elasticity of demand – the extent to which rising prices of a product cause unit sales to decline because of substitution to other products. This reduced cross-price elasticity, in turn, gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including Amitiza.

215. Before January 4, 2021, Takeda had monopoly power in the market for Amitiza because it had the power to exclude competition and/or raise or maintain the price of lubiprostone at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable. From January 4, 2021 through December 31, 2022, Takeda and Par combined had and will continue to have substantial market power in the market for Amitiza and its generic equivalent, because they had and will have the power to exclude competition and/or raise or maintain the price of lubiprostone at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable.

216. Before January 4, 2021, a small but significant, non-transitory increase to the price of brand Amitiza would not have caused a significant loss of sales. From January 4, 2021 through December 31, 2022, a small but significant, non-transitory increase in the price of generic Amitiza would not have caused and will not cause a significant loss of sales.

217. Brand Amitiza does not exhibit significant, positive cross-elasticity of demand

with respect to price with any other lubiprostone product or any other drug used to treat constipation or IBS other than AB-rated generic versions of Amitiza.

218. Brand Amitiza is differentiated from all other lubiprostone products, and all other drugs used to treat constipation and IBS, other than the AB-rated generic versions of Amitiza.

219. Takeda (and, later, Takeda and Par) needed to control only brand Amitiza and its AB-rated generic equivalents, and no other products, in order to maintain the price of lubiprostone profitably at supracompetitive prices. Only the market entry of competing, AB-rated generic versions of Amitiza would render the defendants unable to profitably maintain their prices for Amitiza and generic Amitiza without losing substantial sales.

220. For several years, Takeda sold brand Amitiza at prices well in excess of marginal costs and in excess of the competitive price, and therefore, Takeda had high profit margins.

221. From January 2021 through the present, Par sold AG Amitiza at prices well in excess of marginal cost and in excess of the competitive price, and therefore, Par had high profit margins.

222. From the present through December 2022, Par will sell AG Amitiza at prices well in excess of marginal cost and in excess of the competitive price, and therefore, Par will continue to have high profit margins.

223. Takeda and Sucampo had, and exercised, the power to exclude generic competition to brand Amitiza.

224. Takeda Sucampo, and Par had and will continue to have, and exercised and will continue to exercise, the power to exclude generic competition to the Par-marketed AG.

225. At all material times, high barriers to entry, including regulatory protections

and high costs of entry and expansion, protected brand Amitiza from the forces of price competition.

226. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show the defendants' ability to control the price of brand Amitiza and generic Amitiza, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, inter alia, the following facts: (i) generic Amitiza would have entered the market at a much earlier date, at a substantial discount to brand Amitiza, but for defendants' anticompetitive conduct; (ii) Takeda's gross margin on Amitiza (including the costs of marketing and its share of Sucampo's ongoing research/development costs) at all relevant times was very high; and (iii) Takeda never lowered the price of Amitiza to the competitive level in response to the pricing of other brand or generic drugs.

227. To the extent proof of monopoly power by defining a relevant product market is required, plaintiffs allege that the relevant antitrust market is the market for Amitiza and its AB-rated generic equivalents.

228. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

229. Takeda's market share in the relevant market was 100% until January 4, 2021, after which Takeda and Par, collectively, had and will have 100% market share in the relevant market until January 1, 2023, when Dr. Reddy's, Amneal, Teva, Sun, and Zydus will be able to launch generic Amitiza products.

VIII. MARKET EFFECTS AND DAMAGES TO THE CLASS

230. The defendants willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. The defendants designed a scheme

to delay entry of generic competitors, to further Takeda's anticompetitive purpose of forestalling generic competition against Amitiza, in which Par cooperated in order to increase its own profits. The defendants carried out the scheme with the anticompetitive effect of maintaining supra-competitive prices for the relevant product.

231. The defendants implemented the scheme as described herein. These acts, in combination and individually, were undertaken to serve the defendants' anticompetitive goals.

232. The defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Amitiza, and later the Par-marketed AG Amitiza, from competition. These actions allowed the defendants to maintain a monopoly and exclude competition in the market for brand Amitiza and its generic equivalent, to the detriment of the plaintiffs and all other members of the direct purchaser class.

233. The defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Takeda to sell brand Amitiza without generic competition, and then for Par to sell AG Amitiza without generic competition. Were it not for the defendants' illegal conduct, one or more generic versions of Amitiza would have entered the market sooner, Par would have launched its own generic instead of marketing the AG, and that Par generic would have faced competition during its 180-day exclusivity period from an authorized generic.

234. By way of example, and not limitation, in the absence of the defendants' conduct: (i) Par would have launched its generic Amitiza no later than January 2016 after winning its patent litigation with Takeda and Sucampo; (ii) Takeda and Sucampo would have launched an authorized generic to compete with Par's generic; and (iii) six months after Par's launch, in July 2016, there would have been full competition from many other generic manufacturers, resulting in a much cheaper generic Amitiza. Instead, there was no generic competition until January 2021, and then there is, and will be, only the Par-marketed AG on the market through the end

of 2022, and full competition between multiple generics will not actually occur until January 2023.

235. The defendants' illegal acts and conspiracy to delay generic competition for Amitiza caused the plaintiffs and all members of the class to pay more than they would have paid for Amitiza absent this illegal conduct.

236. Typically, generic versions of brand drugs are priced significantly below the brand counterpart. As a result, upon generic entry, direct purchasers substitute generic versions of the drug for some or all of their brand purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and the brand drug continues to lose even more market share to the generics. This price competition enables all direct purchasers of the drug to purchase generic versions at a substantially lower price, and/or purchase the brand drug at a reduced price. Consequently, brand drug manufacturers have a keen financial interest in delaying the onset of generic competition.

237. Generic companies holding first-to-file exclusivity likewise have a keen financial interest in delaying their entry into the market in exchange for (i) maintaining generic exclusivity and (ii) a share of the monopoly profits that their delay makes possible. Additionally, purchasers experience substantial cost inflation from these delays, since they have to pay full price for the brand version of the drug over that period instead of a much cheaper price for generics.

238. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, direct purchasers, such as the plaintiffs and members of the class, would have paid less for Amitiza by (i) paying lower prices for their remaining brand purchases of Amitiza, (ii) substituting purchases of less-expensive generic

Amitiza for their purchases of more-expensive brand Amitiza, and/or (iii) purchasing generic Amitiza at lower prices sooner.

239. Thus, the defendants' unlawful conduct deprived the plaintiffs and members of the class of the benefits from the competition that the antitrust laws are designed to ensure.

240. Through Takeda's anticompetitive and unlawful settlement agreements with Par and other generic companies, generic competition was impaired in multiple ways: (1) the entry of Par's generic or AG Amitiza was delayed until January 1, 2021, (2) when Par did enter the market with a generic, the agreement effectively ensured that there wouldn't be competition between a Par generic and an AG generic, which was a de facto no-AG agreement, and (3) the other generic companies agreed to a January 1, 2023 entry date, when otherwise they would have been able to enter as of July 2021.

241. In the absence of those anticompetitive and unlawful agreements, (1) Par would have entered the market at a much earlier date with generic Amitiza, (2) Par's generic Amitiza would have faced competition from an AG Amitiza, and (3) competition from many other generics would have followed 180 days after Par's entry.

242. Therefore, these anticompetitive and unlawful agreements (1) allowed Takeda to continue to monopolize the market with brand Amitiza for several years without facing generic competition, and (2) allowed Par's AG, to be the only generic on the market for two years, and therefore being able to charge a price substantially higher than what it would have been in the event of competition from an authorized generic for the first 180 days and then from many generic competitors.

243. Were it not for the defendants' anticompetitive conduct, the plaintiffs and other members of the class would have: (1) purchased lower-priced generic Amitiza, instead of higher-priced brand Amitiza, during the likely several-year period when Par's entry to the

market was delayed, (2) paid a lower price for generic Amitiza during Par's 180-day exclusive period, since there would have been competition between a Par generic and an AG, and (3) paid lower prices for generic Amitiza after Par's 180-day exclusive period expired, since multiple other generics would have entered the market right then, and not a year and a half later.

244. As a consequence, the plaintiffs and other members of the class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

IX. ANTITRUST IMPACT AND EFFECT ON INTERSTATE COMMERCE

245. During the relevant time period, the defendants manufactured, sold, and shipped Amitiza and generic Amitiza across state lines in an uninterrupted flow of interstate commerce.

246. During the relevant time period, the plaintiffs and members of the class purchased substantial amounts of Amitiza and/or AG Amitiza directly from the defendants. As a result of the defendants' illegal conduct, the plaintiff and the members of the class were compelled to pay, and did pay, artificially inflated prices for Amitiza and AG Amitiza.

247. During the relevant time period, the defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All the defendants engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce.

248. The defendants' conduct was within the flow of, and was intended to have and did have a substantial effect on, interstate commerce in the United States, including in this District.

249. During the class period, each defendant, or one or more of each defendant's affiliates, used the instrumentalities of interstate commerce to join or effectuate the scheme.

The scheme in which the defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

X. CONTINUING VIOLATIONS AND FRAUDULENT CONCEALMENT

250. A cause of action accrued for the direct purchaser plaintiffs each time defendants sold a product to direct purchaser plaintiffs at a supra-competitive price made possible by their anticompetitive conduct. And each sale by defendants of a product at a supra-competitive price constituted another overt act in furtherance of their anticompetitive scheme. Accordingly, even though the Par Settlement Agreement was entered into more than four years prior to the filing of this lawsuit, direct purchaser plaintiffs are entitled to recover all damages on all sales that defendants made to direct purchaser plaintiffs at supra-competitive prices within four years of the filing of this lawsuit.

251. Due to defendants' concealment of their unlawful conduct, however, direct purchaser plaintiffs and members of the class are entitled to recover damages reaching back even beyond four years of the filing of this complaint. That Takeda and Sucampo paid Par in the form of an effective no-AG promise was not discoverable until after Par launched AG Amitiza on January 4, 2021, and at which point neither Takeda, Sucampo, nor any other licensed third party launched another authorized generic version of Amitiza, when it became clear that there would not be competition in the generic market for Amitiza and that the settlement agreements were the reason for that. The direct purchaser plaintiffs and members of the class had no knowledge of the defendants' unlawful self-concealing scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence more than four years before the filing of this complaint.

252. This is true because of the nature of the defendants' scheme was self-concealing and because the defendants employed deceptive tactics and techniques of secrecy to avoid

detection of, and to conceal, their contract, combination, conspiracy and scheme.

253. The defendants and co-conspirators wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from plaintiff and members of the class by, among other things:

a. Concealing the details of Takeda agreement with Par that effectively ensured that there would not be generic competition for Takeda for several years in exchange for Par's agreement not to market its ANDA generic or an AG until January 1, 2021;

b. Concealing the fact that the purpose of the de facto no-AG agreement was to provide compensation to Par in connection with the settlement of the patent litigation in order to delay Par's generic entry until January 1, 2021; and

c. Filing documents with the United States Securities and Exchange Commission that failed to disclose the actual substance of the agreements made, as the relevant agreements were either not filed publicly or had significant terms redacted, and were not described in sufficient detail in annual or quarterly reports, 8-K filings, or press releases for plaintiffs to be on notice of the anticompetitive nature of those agreements.

254. Because the scheme and conspiracy were both self-concealing and affirmatively concealed by the defendants, the direct purchaser plaintiffs and members of the class had no knowledge of the scheme and conspiracy more than four years before the filing of this complaint; nor did they have the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed.

255. The direct purchaser plaintiffs and members of the class also lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred. Reasonable diligence on the part of the direct purchaser plaintiffs and members of the class would not have uncovered those facts more than four years before the filing of this complaint.

256. As a result of the defendants' fraudulent concealment, all applicable statutes of

limitations affecting the plaintiff's and class members' claims have been tolled.

XI. CLAIMS FOR RELIEF

COUNT ONE – VIOLATION OF 15 U.S.C. §1 (AGAINST TAKEDA AND PAR)

257. The direct purchaser plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

258. Takeda and Par violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Amitiza and its generic equivalents.

259. Direct purchasers have been injured in their business or property by the violation of 15 U.S.C. § 1. The direct purchasers' injury consists of having paid higher prices for lubiprostone than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes the defendants' conduct unlawful. FWK, as an assignee of direct purchaser Frank W. Kerr Co., and Meijer, as an assignee of direct purchaser McKesson, are the proper entities to bring a case concerning this conduct.

260. From the launch of brand Amitiza in 2006 through January 3, 2021, Takeda possessed monopoly power in the relevant market – i.e., the market for sales of lubiprostone in the United States. But for the defendants' wrongful conduct, as alleged herein, Takeda should have lost its monopoly power in the relevant market as early as January 1, 2016 and in any event well before January 3, 2021.

261. On or about Oct. 2014, Takeda and Par entered into a reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under which Takeda paid Par substantial consideration in exchange for Par's agreement to delay bringing its generic version of Amitiza to the market, the purpose and effect of which were to: (i) delay

generic entry of Amitiza in order to lengthen the period in which Takeda's brand Amitiza could monopolize the market and make supra-competitive profits; (ii) ensure that there would not be competition between a Par generic and an AG during Par's generic exclusivity period, thereby allowing Par to monopolize the generic market for Amitiza during that period, and allowing Par to make supra-competitive profits; and (iii) raise and maintain the prices that the direct purchaser plaintiffs and other members of the class would pay for Amitiza at supra-competitive levels until at least December 31, 2022.

262. From January 1, 2021 through December 31, 2022, Takeda has shared and will continue to share its monopoly power with Par, and the two companies jointly maintained an illegal monopoly throughout that time.

263. The Par Settlement Agreement's reverse payment agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

264. Takeda and Par are liable for this reverse payment agreement under a "rule of reason" standard under the antitrust laws.

265. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

266. As a direct and proximate result of Takeda and Par's anticompetitive conduct, including the reverse payment, the direct purchaser plaintiffs were harmed.

COUNT TWO – VIOLATION OF 15 U.S.C. §2 FOR MONOPOLIZATION (AGAINST TAKEDA)

267. The direct purchaser plaintiffs hereby repeat and incorporate by reference each

preceding and succeeding paragraph as though fully set forth herein.

268. Takeda possessed monopoly power in the market for lubiprostone.

269. Takeda engaged in an exclusionary conduct scheme that involved (i) participating in the filing of a sham Citizen Petition for the purpose of impairing market entry of generic Amitiza products; and (ii) paying Par to abandon its patent challenge and agree to delay its generic entry.

270. The goal, purpose, and/or effect of Takeda's scheme was to maintain and extend its monopoly power with respect to Amitiza. Takeda's illegal scheme to delay the introduction of generic Amitiza allowed it to continue charging supra-competitive prices for the drug without a substantial loss of sales.

271. During the relevant period, the plaintiffs and the class purchased substantial amounts of Amitiza directly from Takeda. As a result of Takeda's illegal conduct, the plaintiffs and the members of the class were compelled to pay, and did pay, artificially inflated prices for Amitiza.

272. The plaintiffs and all class members paid prices for Intuniv that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (i) class members were deprived of the opportunity to purchase lower-priced generic Amitiza instead of the more expensive brand Amitiza; and/or (ii) the price of brand Amitiza and generic Amitiza were artificially inflated by Takeda's illegal conduct.

273. The anticompetitive consequences of Takeda's actions far outweigh any arguable procompetitive benefits. Takeda acquired and extended a monopoly through unlawful means.

274. Takeada's scheme was, in the aggregate, an act of monopolization undertaken with the specific intent to monopolize the market for Amitiza and generic Amitiza in the United

States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

XII. DEMAND FOR JUDGMENT

275. WHEREFORE, the direct purchaser plaintiffs, on behalf of themselves and the proposed class, respectfully demand that this Court:

a. Determine that this action may be maintained as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the class, and declare the direct purchaser plaintiffs as the representatives of the class;

b. Enter joint and several judgments against the defendants and in favor of the direct purchaser plaintiffs and the class;

c. Award the class damages (i.e., three times overcharges) in an amount to be determined at trial;

d. Award the direct purchaser plaintiffs and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

e. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XIII. JURY DEMAND

276. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the direct purchaser plaintiffs, on behalf of themselves and the proposed class, demand a trial by jury on all issues so triable.

Dated: June 25, 2021

Respectfully submitted,
/s/Thomas M. Sobol

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